Complete Summary

GUIDELINE TITLE

Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 16: bone graft extenders and substitutes.

BIBLIOGRAPHIC SOURCE(S)

Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, Mummaneni P, Watters WC 3rd, Wang J, Walters BC, Hadley MN, American Association of Neurological Surgeons/Congress of Neurological Surgeons. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 16: bone graft extenders and substitutes. J Neurosurg Spine 2005 Jun;2(6):733-6. [8 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Degenerative disease of the lumbar spine

GUIDELINE CATEGORY

Management
Technology Assessment

CLINICAL SPECIALTY

Internal Medicine
Neurological Surgery
Orthopedic Surgery

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians

GUIDELINE OBJECTIVE(S)

To examine the medical evidence regarding the use of bone graft substitutes in lumbar spinal surgery

TARGET POPULATION

Patients with degenerative disease of the lumbar spine undergoing lumbar fusion

INTERVENTIONS AND PRACTICES CONSIDERED

1. Use of autologous bone or recombinant human bone morphogenetic protein (rhBMP-2) bone graft substitute in conjunction with a threaded titanium cage
2. Use of rhBMP-2 in combination with hydroxyapatite (HA) and tricalcium phosphate in some cases of posterolateral fusion (PLF)
3. Calcium phosphate formulations as bone graft extenders

MAJOR OUTCOMES CONSIDERED

- Effectiveness of bone graft extenders and substitutes in terms of fusion rates and clinical outcomes
- Safety of bone graft extenders and substitutes

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

An electronic search of the database of the National Library of Medicine from 1966 to November 2003 was performed using the search terms "bone graft substitute" as a key word and then again as the search focus. The search was repeated using search terms "bone substitutes," "tricalcium phosphate," "calcium phosphate," "bone morphogenetic protein," and "hydroxyapatite" combined with "spine" and "lumbar." The search was limited to the English language and to reports on

humans. The results of the searches were combined, and a total of 54 articles were identified and reviewed. The reference lists of each of these papers were reviewed, and further references were identified and subsequently submitted for review. The vast majority of references found included animal data and were therefore eliminated. There were also several papers dealing with cervical interbody fusion and scoliosis. Ultimately, six papers were identified as providing Class III or better data regarding the use of bone substitutes in lumbar fusion for degenerative disease. These papers are described in Table 1 in the original guideline document.

NUMBER OF SOURCE DOCUMENTS

6 papers were identified as providing Class III or better data regarding the use of bone substitutes in lumbar fusion for degenerative disease.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Classes of Evidence

Class I Evidence from one or more well-designed, randomized controlled clinical trials, including overviews of such trials

Class II Evidence from one or more well-designed comparative clinical studies, such as nonrandomized cohort studies, case-control studies, and other comparable studies, including less well-designed randomized controlled trials

Class III Evidence from case series, comparative studies with historical controls, case reports, and expert opinion as well as significantly flawed randomized controlled trials

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The group culled through literally thousands of references to identify the most scientifically robust citations available concerning each individual topic. Not every reference identified is cited. In general, if high-quality (Class I or II) medical evidence was available on a particular topic, poorer-quality evidence was only briefly summarized and rarely included in the evidentiary tables. If no high-quality evidence existed, or if there was significant disagreement between similarly classified evidence sources, then the Class III and supporting medical evidence were discussed in greater detail. If multiple reports were available that provided similar information, a few were chosen as illustrative examples.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In January 2003, a group was formed at the request of the leadership of the Congress of Neurological Surgeons (CNS) by the executive committee of the American Association of Neurological Surgeons/CNS Joint Section on Disorders of the Spine and Peripheral Nerves to perform an evidence-based review of the literature on lumbar fusion procedures for degenerative disease of the lumbar spine and to formulate treatment recommendations based on this review. In March 2003, this group was convened. Invitations were extended to approximately 12 orthopedic and neurosurgical spine surgeons active in the Joint Section or in the North American Spine Society to ensure participation of nonneurosurgical spine surgeons. The recommendations that were developed represent the product of the work of the group, with input from the Guidelines Committee of the American Association of Neurological Surgeons/CNS and the Clinical Guidelines Committee of North American Spine Society.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

Standards Recommendations of the strongest type, based on Class I evidence reflecting a high degree of clinical certainty

Guidelines Recommendations based on Class II evidence reflecting a moderate degree of clinical certainty

Options Recommendations based on Class III evidence reflecting unclear clinical certainty

COST ANALYSIS

Lumbar fusion may be associated with a high short-term cost, especially if instrumentation is placed; however, there appear to be long-term economic benefits associated with lumbar fusion including resumption of employment. To describe the economic impact of lumbar fusion for degenerative disease adequately, it is important to define the patient population treated with fusion and to compare efficacy as well as the costs of other treatment alternatives. Any such analysis should include both short- and long-term costs and benefits.

See "Part 3: assessment of economic outcome" in the "Availability of Companions Documents" field for the complete analysis.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The committee presents data that have been reviewed by the major organizations representing neurological surgery and orthopedic surgery. The Board of Directors of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) Executive Committee have reviewed these Lumbar Fusion Guidelines and formally voted their approval. In addition, input and approval was received and greatly appreciated from the AANS/CNS Guidelines committee.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of recommendations (standards, guidelines, and options) and classes of evidence (I–III) are defined at the end of the "Major Recommendations" field.

Standards. The use of autologous bone or recombinant human bone morphogenetic protein (rhBMP-2) bone graft substitute is recommended in the setting of an anterior lumbar interbody fusion (ALIF) in conjunction with a threaded titanium cage.

Guidelines. There is insufficient evidence to recommend a treatment guideline.

Options 1) Recombinant human BMP-2 in combination with hydroxyapatite (HA) and tricalcium phosphate may be used as a substitute for autograft bone in some cases of posterolateral fusion (PLF). 2) Several formulations of calcium phosphate exist and are recommended as bone graft extenders, especially when used in combination with autologous bone.

Summary

Despite the large volume of animal data regarding the use of synthetic bone graft substitutes or extenders, there are very few data regarding the use of these substances for fusion in lumbar degenerative disease. The best available data indicate that rhBMP-2 is a viable alternative to autograft bone for interbody fusion procedures. This same substance may also be a viable alternative to autograft for posterolateral fusion; however, definitive medical evidence is not yet available. There is little, if any, medical evidence to support the use of other biological agents at the present time. As promising new compounds are brought to market, well-designed cohort studies and randomized trials will be required to determine the actual usefulness of these compounds in clinical practice. It is important not to generalize the results obtained with one preparation or application to different preparations or applications.

The use of synthetic calcium phosphate ceramics as graft extenders appears to be reasonable in certain situations. The medical evidence available regarding their use is limited and of poor quality. Further study will be required to establish their utility for use in spinal fusion.

Definitions:

Grades of Recommendation

Standards Recommendations of the strongest type, based on Class I evidence reflecting a high degree of clinical certainty

Guidelines Recommendations based on Class II evidence reflecting a moderate degree of clinical certainty

Options Recommendations based on Class III evidence reflecting unclear clinical certainty

Classes of Evidence

Class I Evidence from one or more well-designed, randomized controlled clinical trials, including overviews of such trials

Class II Evidence from one or more well-designed comparative clinical studies, such as nonrandomized cohort studies, case-control studies, and other comparable studies, including less well-designed randomized controlled trials

Class III Evidence from case series, comparative studies with historical controls, case reports, and expert opinion as well as significantly flawed randomized controlled trials

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of bone graft extenders and substitutes in lumbar fusion procedures

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The use of synthetic calcium phosphate ceramics as graft extenders appears to be reasonable in certain situations. The medical evidence available regarding their use is limited and of poor quality. Further study will be required to establish their utility for use in spinal fusion.
- The strength of an evidence-based document is only as strong as the foundation on which it is built. This comprehensive document chronicles the state of scientific information in 2005. Many of the published reviews presented flawed results due to poorly defined outcome measures, inadequate numbers of patients, and comparison of dissimilar treatment groups. These studies of "apples and oranges" gleaned little scientific information; therefore, for the purpose of this review, the authors have discarded Class III studies whenever stronger scientific evidence was available. The result is that most of the published studies on lumbar fusion were not included on this document. When Class I or II scientific evidence was available, standards and guidelines were formulated; however, in most cases, the scientific data were only adequate to support recommendations for treatment options. The aforementioned results do not detract from the importance of this document; rather, the need for the neurosurgical community to design and complete prospective randomized controlled studies to answer the many lingering clinical questions with rigorous scientific power can clearly be seen. As more data continue to be accumulated, revisions of this document will be needed.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, Mummaneni P, Watters WC 3rd, Wang J, Walters BC, Hadley MN, American Association of Neurological Surgeons/Congress of Neurological Surgeons. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine.

Part 16: bone graft extenders and substitutes. J Neurosurg Spine 2005 Jun;2(6):733-6. [8 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Jun

GUIDELINE DEVELOPER(S)

American Association of Neurological Surgeons - Medical Specialty Society
Congress of Neurological Surgeons - Professional Association

SOURCE(S) OF FUNDING

This project was funded entirely by a grant from AANS/CNS Section on Disorders of the Spine. No funding was received from any commercial entity to support the production or publication of these guidelines.

GUIDELINE COMMITTEE

Guidelines Committee of the American Association of Neurological Surgeons/Congress of Neurological Surgeons (CNS)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: Daniel K. Resnick, MD; Tanvir F. Choudhri, MD; Andrew T. Dailey, MD; Michael W. Groff, MD; Larry Khoo, MD; Paul G. Matz, MD; Praveen Mummaneni, MD; William C. Watters III, MD; Jeffery Wang, MD; Beverly C. Walters, MD, MPH; Mark N. Hadley, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

North American Spine Society - Medical Specialty Society

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Web site.

Print copies: Available from Daniel K. Resnick, M.D., Department of Neurological Surgery, University of Wisconsin Medical School, K4/834 Clinical Science Center, 600 Highland Avenue, Madison, Wisconsin 53792; Email: Resnick@neurosurg.wisc.edu.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Introduction to the guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. 2005 Jun. 1 p. Available in Portable Document Format (PDF) from the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Web site.
- Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 1: introduction and methodology. 2005 Jun. 2 p. Available in Portable Document Format (PDF) from the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Web site.
- Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 3: assessment of economic outcome. 2005 Jun. 6 p. Available in Portable Document Format (PDF) from the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Web site.

Print copies: Available from Daniel K. Resnick, M.D., Department of Neurological Surgery, University of Wisconsin Medical School, K4/834 Clinical Science Center, 600 Highland Avenue, Madison, Wisconsin 53792; Email: Resnick@neurosurg.wisc.edu.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on January 8, 2007. The information was verified by the guideline developer on January 29, 2007.

COPYRIGHT STATEMENT

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 9/15/2008